

Hydrochlorothiazide and use during pregnancy

Final SPC and PIL wording agreed by PhVWP June 2008

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SPC

Section 4.6

“There is limited experience with hydrochlorothiazide during pregnancy, especially during the first trimester. Animal studies are insufficient.

Hydrochlorothiazide crosses the placenta. Based on the pharmacological mechanism of action of hydrochlorothiazide its use during the second and third trimester may compromise foeto-placental perfusion and may cause foetal and neonatal effects like icterus, disturbance of electrolyte balance and thrombocytopenia.

Hydrochlorothiazide should not be used for gestational oedema, gestational hypertension or preeclampsia due to the risk of decreased plasma volume and placental hypoperfusion, without a beneficial effect on the course of the disease.

Hydrochlorothiazide should not be used for essential hypertension in pregnant women except in rare situations where no other treatment could be used.

Package Leaflet

Pregnancy and breastfeeding

You must tell your doctor if you are pregnant or if you think that you are. Usually, your doctor will advise you to take another medicine instead of [product], as [product] is not recommended during pregnancy. This is because [product] crosses the placenta and its use after the third month of pregnancy may cause potentially harmful foetal and neonatal effects.